EC-2000-007

ROPES & GRAY

ONE FRANKLIN SQUARE 1301 K STREET, NW SUITE 800 EAST WASHINGTON, DC 20005-3333

PHONE: (202) 626-3900 FAX: (202) 626-3961 DIRECT DIAL: (202) 626-3905 MGREENWOOD@ROPESGRAY.COM

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United States Environmental Protection Agency Enforcement and Compliance Docket and Information Center (Mail Code 2201A) Attention: Docket Number EC-2000-007 1200 Pennsylvania Avenue, NW 4th Floor, Room 4033 Washington, DC 20004

To Whom It May Concern:

On behalf of the Coalition for Effective Environmental Information, I am submitting these comments on the proposed Cross-Media Electronic Reporting and Recordkeeping Rule that was first proposed in the Federal Register at 66 Fed. Reg. 46162 (August 31, 2001). Thank you for your attention to this matter.

Sincerely,

Mark a. Greenwood /she

MAG/chh: 7121370

Enclosures (Orig. & 3 Copies of Comments)

Before the United States Environmental Protection Agency

Proposed Rulemaking on the Cross-Media Electronic Reporting and Recordkeeping Rule

Docket Number EC-2000-007

Comments of the Coalition for Effective Environmental Information

On August 31, 2001, the U.S. Environmental Protection Agency (EPA) issued a Federal Register notice (66 Fed. Reg. 46162) requesting comment on a proposed rule, commonly referred to as the Cross-Media Electronic Reporting and Recordkeeping Rule (CROMERRR). Under the proposed rule, any party that submits an electronic document or keeps an electronic record to satisfy an EPA requirement would need to meet a set of new information technology requirements affecting its software and hardware systems.

The Coalition for Effective Environmental Information (CEEI) is a group of major companies and business organizations, representing a wide range of industry sectors, that share a common interest in improving how the government collects, manages, uses and disseminates environmental information. CEEI supports public policies that encourage data quality, governmental accountability, efficient data collection, alignment of data with strategic goals and consistent management of environmental information resources.

CEEI has been a strong supporter of EPA's efforts to move toward policies and systems that facilitate electronic reporting and recordkeeping. We believe that "egovernment" can have very positive benefits for the public. For those who submit environmental information to the government, electronic reporting and recordkeeping initiatives can increase the efficiency of reporting. These initiatives are most productive when they are aligned with efforts to consolidate and streamline the underlying reporting and recordkeeping requirements themselves. In addition, electronic reporting can improve the quality of the data that EPA uses and disseminates. Electronic submissions often remove the opportunities for human error in data transfers that have contributed to past data accuracy problems at the Agency.

For these reasons, CEEI was encouraged by EPA's early efforts to develop CROMERRR. As EPA explained this rule to the public, CROMERRR was intended to remove the regulatory obstacles to electronic reporting and recordkeeping. We have supported, and will continue to support, that aspect of the rulemaking.

Unfortunately, our review of the proposed rule indicates that EPA has decided to use CROMERRR to pursue other objectives that have added new complexity and

¹ CEEI includes representatives from the aerospace, chemical, energy, automobile, pharmaceutical, forest products, petroleum, electronics and consumer products industries.

tremendous burdens for those who must submit and keep information for EPA purposes. After reviewing the specifics of this proposed rule, we must conclude that CROMERRR is fundamentally flawed. It cannot be justified on the record that EPA has provided to support the rule. It is also fundamentally inconsistent with the statutes under which it has been written.

As a broader policy matter, CROMERRR represents a major setback to the broad consensus that has developed among stakeholder groups in support of electronic reporting and recordkeeping initiatives at EPA. Under CROMERRR those who report and keep information for EPA purposes are facing major costs associated with using electronic media. For the business community, CROMERRR will transform electronic records from an opportunity for more efficient compliance to a major, unjustified regulatory burden. For all these reasons, CEEI believes that the proposed rule should be withdrawn.

In these comments, CEEI will focus on the issues associated with the recordkeeping aspects of CROMERRR.² The comments begin with a characterization of CROMERRR. We then analyze the three apparent goals of CROMERRR and indicate why the record is insufficient to support the rule and why EPA's actions are legally flawed. As part of this analysis, CEEI offers its recommendations for how EPA should proceed to address its expressed concerns.

The Net Effect of CROMERRR

CROMERRR establishes requirements for both reporting and recordkeeping. Yet reporting has always been the primary focus of Congressional and Executive Branch activities in the e-government area. One of the driving forces for the issuance of CROMERRR is EPA's intent to comply with the Government Paperwork Elimination Act (GPEA).³ While the statute does call for actions to empower "electronic maintenance" of information, the focus of this statute was to facilitate electronic reporting to the government. The statute and legislative history, for example, show a particular interest in resolving questions about the use of electronic signatures on government forms.⁴

Similarly, EPA's record on CROMERRR indicates that it has focused primarily on the reporting aspects of the rule. The docket for this rule has only a few documents that make any reference to the recordkeeping aspects of the rule. More fundamentally, EPA has not conducted the kind of cost-benefit analysis required by guidance from the Office of Management and Budget (OMB) or recommended by the Department of Justice

² Many of our members also have concerns about the reporting aspect of the rule as well. Our members, as well as other participants in this rulemaking, will make those concerns known to EPA through separate comments.

³ P.L. 105-277 (Note at 44 U.S.C. § 3504).

⁴ See sections 1703 and 1706 of GPEA.

(DOJ) on the recordkeeping aspect of the rule.⁵ As a result of this "stepchild" status for the recordkeeping aspects of the rule, the record for the proposed rule does not begin to reflect the major cost implications of CROMERRR.

It is notable that most other agencies have not attempted to establish requirements for electronic recordkeeping by private parties. Consistent with the primary thrust of GPEA, other agencies have focused on electronic reporting to the government. The one agency that did issue a rule with the same scope as CROMERRR, the Food and Drug Administration (FDA), did so for a much smaller universe of highly regulated companies. Moreover, the FDA has discovered that its rule, which was issued in 1997, has been extremely difficult to implement, even though it affected a much smaller universe of private companies than does CROMERRR. Thus in proposing CROMERRR EPA is pursuing perhaps the most sweeping effort ever attempted by the federal government to regulate the structure of electronic recordkeeping systems in the private sector.

One of the most fundamental problems with EPA's approach to this matter is that it is imposing new obligations on existing practices and declaring those obligations voluntary. EPA states emphatically at the beginning of the preamble to the proposal:

These proposed requirements will apply to regulated entities that choose to submit electronic documents and/or keep electronic records, and under today's proposal, the choice of using electronic rather than paper for future reports and records will remain purely voluntary.

This perception that the recordkeeping requirements will be voluntary was critical to EPA's conclusions that the rule will not impose any significant cost. EPA's cost-benefit analysis of CROMERRR is based on the assumption that only 0.5% of EPA-

⁵ OMB, "Implementation of the Government Paperwork Elimination Act," http://www.whitehouse.gov/omb/fedreg/gpea2.html (hereafter "OMB Guidance"); DOJ, "Legal Considerations in Designing and Implementing Electronic Processes: a Guide for Federal Agencies," (November 2000), (hereafter "DOJ Guidance").

Other federal agencies have not promulgated comprehensive regulations, like CROMERRR, for implementing GPEA. Other agencies have focused on electronic transmission of documents, rather than electronic recordkeeping. See e.g., 66 Fed. Reg. 45792 (electronic filing of trademark applications with PTO); 66 Fed. Reg. 60132 (HUD proposal for electronic submission of financial information from lenders); 65 Fed. Reg. 57088 (electronic filing of documents in proceedings before the Federal Energy Regulatory Commission). Moreover, these agencies have tailored their rules to particular programs or document submission requirements. See id.

⁷ See 62 Fed. Reg. 13461 (March 20, 1997) for FDA's estimate of the impact of the Part 11 rules.

⁸ FDA's Website on Part 11, at http://www.21cfrpart11.com/pages/poll_results/index.htm, presents a poll conducted in 2001by NuGenesis Technologies Corporation characterizing Part 11 compliance. Only 11% of respondents indicated that "all or most" of their systems were compliant with Part 11. In contrast, 20% of respondents indicated that they hadn't started yet and 14% indicated that they did not know if they were compliant.

⁹ 66 Fed. Reg. 46163.

regulated facilities would comply with the recordkeeping aspect of the rule. ¹⁰ This conclusion was based on an analysis showing that the costs of electronic recordkeeping under CROMERRR would outweigh the benefits of CROMERRR for most EPA-regulated facilities.

The reality of private sector operations differs substantially from what EPA has presented in this rule. Electronic recordkeeping is actually standard practice in most firms in the United States, whether large or small. This more accurate picture of recordkeeping practices is demonstrated in the comments of many other parties to this rulemaking. 12

For many years companies have assumed that they may comply with EPA recordkeeping requirements through electronic records. EPA regulations have generally been silent on the question of whether paper or electronic formats for records were acceptable. Those regulations that call for "written" records can certainly be satisfied with electronic records. ¹³

To the extent that there could have been a question about the acceptability of electronic records to satisfy EPA requirements, that ambiguity has been resolved by the practice of EPA and state enforcement personnel. Every year compliance personnel from a variety of environmental agencies conduct thousands of inspections of facilities that are subject to EPA regulations. These inspections commonly include a review of the facility records. These inspectors routinely review, copy and accept facility records that are kept in electronic formats.

The widespread use of electronic systems to generate and keep company records has been ongoing for well over a decade. If there were any major questions about the acceptability of electronic records for EPA compliance purposes, those policy questions would have surfaced long before now. In short, by the action of state and EPA inspectors, the Agency has eliminated any ambiguity that may have existed about the acceptability of electronic records to meet EPA requirements.

The existing practice in industry has been to keep EPA-related records in an electronic format, just as companies have been doing for all of their records. Other commenters have documented examples of the types of electronic records they keep that contain EPA-required information.¹⁴ CROMERRR imposes requirements that exceed the

¹⁰ Logistics Management Institute, "Cross-Media Electronic Reporting and Records Rule: Cost-Benefit Analysis," EP908T2 (March 2001), at 3-8.

This is particularly the case with the very broad definition of "electronic record" found in the proposed rule. The definition of "electronic record" in the proposed rule means "any combination of text, graphics, data, audio, pictorial, or other information that is created, modified, maintained, archived, retrieved or distributed by a computer system." See §3.3 of Proposed Rule.

¹² See comments of American Petroleum Institute, Procter & Gamble Company, Dow Chemical Company, American Chemistry Council, and Edison Electric Institute.

¹³ The DOJ Guidance, at 13, notes, "A statutory 'writing' requirement does not necessarily imply that this writing must be on paper."

¹⁴See comments identified in fn. 11.

capability of the vast majority of existing information systems. Companies would have to make new investments in software and hardware, as well as set up new management systems, to meet CROMERRR. Thus EPA is imposing new requirements on existing recordkeeping practices. Such requirements are not voluntary in any meaningful sense.

While GPEA is cited as the statutory basis for CROMERRR, EPA is actually pursuing multiple goals in this rulemaking, some of which exceed the GPEA mandate. There appear to be three primary objectives that EPA has in mind. First, EPA is seeking to "remove obstacles" to electronic reporting and recordkeeping. This objective, which relates directly to the GPEA mandate, is a curious pursuit in the case of recordkeeping since, as indicated above, EPA regulations and accepted practice by inspectors allow electronic recordkeeping. CEEI can only assume that EPA is trying to clarify the acceptability of such electronic records with this rule.

Second, EPA has indicated an intent to reduce the potential for fraud in electronic reporting and recordkeeping. This concern appears to be drawn strongly from the concerns expressed in the DOJ Guidance, although EPA does not provide strong independent evidence supporting the need for anti-fraud provisions drawn from the Agency's own experience. EPA's concerns in this regard have influenced several CROMERRR provisions, but they are probably most relevant to the "audit trail" requirements in proposed §3.100(a)(6) and (7).

Third, EPA has imposed requirements designed to assure long-term retention of electronic records. These requirements attempt to address one of the larger challenges of the Information Age. Computer technology changes very rapidly, and it is virtually impossible to anticipate what the major software and hardware systems will look like a decade from now. Institutions throughout our society, including the government itself, have not yet determined how they will manage these changes and assure that appropriate records are archived for future use.

As EPA moves forward in this rulemaking, it is important for the Agency to separate its consideration of these three issues. EPA is at a different point in understanding the nature of the three issues and framing the problem to be solved. Only the first issue, the empowerment of electronic reporting and recordkeeping, is clearly mandated by GPEA and thus subject to the statutory deadline. The CROMERRR requirements that follow from the three objectives differ substantially and have very different cost impacts. Finally, the likely path forward for each issue will be different, both in terms of the information that must be assessed and the likely solutions to consider.

In the remainder of these comments, CEEI will explain the fundamental flaws of CROMERRR in regard to the three apparent purposes of the rule.

CROMERRR is Inconsistent with the Burden Reduction Laws

EPA has not clearly articulated its statutory basis for CROMERRR. In its preamble, EPA indicates that it is issuing CROMERRR in part to comply with the GPEA mandate. GPEA was enacted to supplement the PRA, and thus GPEA has been codified

in the U.S. Code as a Note following 44 U.S.C. §3504.¹⁵ It appears that EPA is invoking both GPEA and PRA as the basis for CROMERRR.¹⁶

Neither of these statutes provides EPA with clear authority to issue a rule such as CROMERRR.¹⁷ Even if these statutes are read to provide EPA with some legal basis to establish standards for electronic reporting and recordkeeping, CROMERRR itself cannot be reconciled with the mandates of these statutes. Both statutes are intended to reduce burdens on the regulated community, an objective that CROMERRR does not serve in any meaningful way.

In enacting GPEA, Congress intended to relieve the private sector of the burdens associated with unnecessary reporting. The statute contemplated that the Executive Branch would, as stated in §1704, provide

- (1) for the option of the electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper; and
- (2) for the use and acceptance of electronic signatures, when practicable. 18

¹⁵ In addition, GPEA §1702 explicitly amended 44 U.S.C. § 3504 of the PRA. In stating its purposes, GPEA specifically provides in §1703(a), §1704, §1705 and §1706(a) that the actions of OMB under the statute are intended to "fulfill the responsibility to administer the functions assigned under chapter 35 of title 44, United States Code [the PRA]."

¹⁶ In its Regulatory Plan that is published semi-annually in the Federal Register, EPA has identified both GPEA and PRA as its statutory base for CROMERRR. See 66 Fed. Reg. 61127 (December 3, 2001), at 61296. In that same notice, EPA also mentions the Electronic Signatures in Global and National Commerce (ESIGN) statute as the "Legal Basis" for CROMERRR. ESIGN's applicability to CROMERRR is discussed in more detail later in these comments.

federal agencies to provide for the option of electronic maintenance, submission or disclosure of information. In fact, GPEA provides no such directive or authority directly to federal agencies. By its terms Section 1704 imposes an obligation on OMB to "ensure" that agencies take action to facilitate electronic reports and recordkeeping. This reference to OMB, rather than individual agencies, was carefully considered by Congress. Early versions of the bills that became the GPEA imposed the obligations to authorize electronic records directly on executive branch agencies. In the Senate, however, the bill was modified at the behest of the Senate Committee on Governmental Affairs to impose the obligation on OMB. As explained by Senator Thompson, "The language which we are discussing today seeks to take advantage of the advances in modern technology to lessen the paperwork burdens on those who deal with the Federal government. This is accomplished by requiring the Office of Management and Budget, through its existing responsibilities under the "Paperwork Reduction Act" and the "Clinger-Cohen Act," to develop policies to promote the use of alternate information technologies..." 144 Cong. Rec. S 11325.

¹⁸ The legislative history of predecessor bills indicates that the Congress was particularly concerned that agencies determine what steps were necessary to allow for the acceptance of electronic signatures.

The burden reduction objectives are quite explicit in the legislative history of the bill. Senator Abraham, a key sponsor of the bill, offered the following explanation of the law's intent:

[The bill] is intended to bring the federal government into the electronic age, in the process saving American individuals and companies millions of dollars and hundreds of hours currently wasted on government paperwork...Each and every year, Mr. President, Americans spend in excess of 6 billion hours simply filling out, documenting and handling government paperwork. This huge loss of time and money constitutes a significant drain on our economy and we must bring it under control.

144 Cong. Rec. S12684-85.

Similar comments can be found in the House debate on H.R. 852, the predecessor bill to GPEA in that body. Examples include the statements of Congresswoman Pryce:

I knew the regulatory burden on small business was heavy to begin with, but I was amazed to learn that the amount of time and effort spent in meeting the Government's paperwork demands has a dollar value roughly equivalent to 9 percent of the Nation's gross domestic product. Congress must lighten this load.

143 Cong. Rec. H990

Comments offered by Congressman Talent reinforced this view:

Paperwork demands of the Federal Government place a tremendous burden upon all Americans. Some estimates place the total burden at more than 6 billion hours a year. To place this staggering number in perspective, 6 billion hours of labor is equivalent to 3 million employees working full-time to satisfy the often repetitive and duplicative requests of various Federal agencies. This is an expense which small business can ill afford.

143 Cong. Rec. H996

In enacting this statute, Congress certainly did not contemplate that federal agencies would be imposing new costs on the public under its auspices. The Senate Report, for example, was quite explicit on this point:

The Committee believes that the bill will not subject any individuals or businesses affected by the bill to any additional regulation... After full implementation of the bill, individuals and businesses will benefit from potential cost savings by having the opportunity to conduct transactions electronically with the Federal government.

Report of the Committee on Commerce, Science, and Transportation, "Government Paperwork Elimination Act," Report 105-335 (September 17, 1998), p. 5.

It is also clear that burden reduction is a core objective of PRA. In defining the responsibilities of federal agencies, the statute provides that agencies must manage information resources to "reduce information collection burdens on the public." For each information collection that agencies conduct, they must certify and provide a record to support certain key findings. In particular, they must certify that the collection request "reduces to the extent practicable and appropriate the burden on the persons who shall provide information to or for the agency."

Furthermore, agencies must certify that the collection activity "is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond." It is also worth noting that the PRA requires agencies to publish information collection requests in the Federal Register and solicit comments on, among other things, how the agency can "minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology." ²²

CROMERRR is unjustified under these statutes and their implementing guidance. CROMERRR will impose overwhelming costs on the regulated community. Reasonable, even conservative, estimates of the cost indicate that this is a multi-billion dollar rule. Very simply, CROMERRR is not a burden reduction regulation.

It is equally clear that CROMERRR is not "consistent and compatible" with existing recordkeeping practices. As indicated elsewhere in these and other comments, electronic recordkeeping is now a standard practice in American business. Very few current information systems can now meet the requirements of CROMERRR. The vast majority of companies would need to undertake a massive investment in new software and hardware to comply, causing major disruptions of existing recordkeeping practices.

EPA has also failed to undertake a serious analysis of the recordkeeping aspects of this rule. The PRA contemplates that an agency will analyze the need for a particular information collection action and provide a "specific, objectively supported estimate of burden." After public review and comment on the collection, the agency must be able to certify, with a supporting record, that the collection meets several tests. EPA would

¹⁹ 44 U.S.C. §3506(b)(1)(A).

²⁰ 44 U.S.C. §3506(c)(3)(C).

²¹ 44 U.S.C. §3506(c)(3)(E).

²² 44 U.S.C. §3506(c)(2)(A)(iv).

²³ 44 U.S.C. §3506(c)(1)(A).

²⁴ 44 U.S.C. §3506(c)(3).

have difficulty justifying CROMERRR under most of the statutory tests, but the Agency would have particular difficulty demonstrating that CROMERRR reduces burdens on reporting entities or is compatible with existing recordkeeping practices.

As an effort to comply with GPEA, CROMERRR also fails to meet the analytical requirements set forth in the OMB Guidance for that statute. The Guidance calls on agencies to assess the risks, costs and benefits of particular electronic reporting and recordkeeping requirements. According to the guidance, "The assessment should develop strategies to mitigate risks and maximize benefits in the context of available technologies, and the relative total costs and effects of implementing those technologies on the program being analyzed." The record provides no evidence that EPA has conducted such a broad-based assessment for the recordkeeping aspects of CROMERRR.

An additional problem with CROMERRR concerns its inconsistency with the requirements of ESIGN. Under ESIGN no signature, contract or other record "with respect to any transaction in or affecting interstate or foreign commerce" may be denied legal effect or validity solely because it is in electronic form. The statute provides, however, that a federal agency may establish requirements "that records be filed with such agency or organization in accordance with specified standards or formats." In exercising this authority, however, federal agencies must comply with the GPEA, which of course contemplates that agencies remove obstacles to electronic reporting and recordkeeping.

In the preamble to CROMERRR, the Agency notes that ESIGN's protections apply to certain types of documents that are used to comply with EPA regulations:

E-SIGN does cover documents that are created in a commercial, consumer, or business transaction, even if those documents are also submitted to a government agency or retained by the regulated community for governmental purposes. For example, an insurance contract that is commemorated in an electronic document will be covered by E-SIGN, even if EPA or an authorized State requires that the policy-holder maintain proof of insurance as part of a federal or State environmental program.²⁸

The universe of business records that may serve EPA purposes is actually quite extensive, including documents such as patents, invoices, shipping papers, production records, quality control records, advertising, information supplied to customers and many other similar documents. These documents are most commonly found in the universe of

²⁵ OMB Guidance, at 9.

²⁶ 15 U.S.C. §7001.

²⁷ 15 U.S.C. §7004(a). The language of this provision refers only to records "filed" with an agency, which indicates that this reserved authority is limited to reporting requirements. The language does not, on its face, cover records maintained by a private party that may be viewed by a governmental inspector.

²⁸ 66 Fed. Reg. 46167.

records used to comply with EPA recordkeeping requirements, rather than reporting requirements.

By the logic of ESIGN, as recognized by EPA, such documents should not be subject to any special requirements, including those contained in CROMERRR, that invalidate them simply because they are in electronic form. Yet EPA does not define what documents fall into the class of "ESIGN documents" nor does it provide any specific exemption for such documents in the rule. Instead EPA offers a broad assertion that the government can set "technology-neutral standards and formats for such records" for governmental purposes. According to EPA, agencies can promulgate such standards for ESIGN documents if those standards are proposed by March 1, 2001. The relevance of this assertion is unclear in this rulemaking, however, since CROMERRR was proposed on August 31, 2001.

Even if EPA were to assert some general authority to establish "standards or formats" for these documents under the authority of §7004(a) of ESIGN, there are several limits on that authority that would negate what the Agency has done in CROMERRR. First, this authority covers records "filed" with the Agency, which would not reach documents that EPA requires to be maintained at a regulated party's facility. Second, §7004(c)(2) stipulates that this provision does not override GPEA, which CROMERRR does not satisfy. Third, any Agency standards or formats otherwise covered under this section would not be valid under §7004(b)(2) unless they are consistent with the mandate of ESIGN to validate electronic records and "will not impose unreasonable costs on the acceptance and use of electronic records." Given the overwhelming cost of CROMERRR, as indicated in these and other comments, EPA could not satisfy these criteria.

Taken as a whole, CROMERRR cannot be legally justified. Under the standards of the Administrative Procedure Act (APA), CROMERRR is arbitrary, capricious and not in accord with the laws under which it was written. It cannot be reconciled with GPEA, PRA or ESIGN.

To satisfy its obligations under GPEA, the best course that EPA can take in relation to its recordkeeping requirements is to leave the status quo in place. EPA regulations now allow electronic recordkeeping and EPA inspectors have been accepting such records for some time. EPA does not need to take any particular action to "allow electronic recordkeeping" as suggested in the preamble to this rule. ²⁹ In effect, EPA should accept one of the primary options identified in its Regulatory Plan for CROMERRR – "a business-as-usual approach to electronic recordkeeping." ³⁰

To the extent that EPA believes that a clarification is needed to indicate that electronic recordkeeping is acceptable under its regulations, EPA could simply make a public statement that mirrors the core provision of ESIGN – no record kept for EPA purposes would be deemed invalid solely because it was kept in an electronic format. Such a statement does not need to be made through a rulemaking. In fact, it has been

²⁹ 66 Fed. Reg. 46164.

³⁰ 66 Fed. Reg. 61296.

common practice at EPA to use a variety of guidance and interpretive mechanisms to set forth its views about what constitutes acceptable compliance with its regulations.

The Anti-Fraud Provisions of CROMERRR Cannot Be Supported

As indicated earlier in these comments, CROMERRR is attempting to address issues well beyond the immediate mandates of GPEA. To satisfy GPEA, agencies are simply required to provide for the option of electronic maintenance, submission of disclosure of information, when practicable as a substitute for paper. The statute makes no reference to enhancing the powers of prosecutors to enforce against recordkeeping fraud.

The preamble to CROMERRR articulates at least three objectives for the rulemaking. These objectives include (1) burden reduction; (2) data quality and speed of data transfer; and (3) "to maintain or improve the level of corporate and individual responsibility and accountability for electronic reports and records that currently exists in the paper environment." The latter reference to improving accountability for electronic records over what is expected of paper records is a telling indication of what CROMERRR seeks to achieve.

EPA's effort to improve accountability leads directly to requirements in CROMERRR that would be very expensive. The primary example is the requirement for "audit trail software." As indicated by many commentators, the software needed to meet this requirement is not generally available at this time, and companies would have to incur major new expenses to integrate such a capability into all of their systems.

In addition, CROMERRR contains other somewhat vague requirements that, depending on their intent, could impose major costs and disruptions on existing practices. For example, proposed §3.100(a)(2) says that electronic records must be maintained "without alteration" for the entirety of the required period of record retention. It is unclear how that standard applies to the normal modification and updating of data files. Does this mean that no document once created can ever be modified? If a company needs to modify a record, must it create a new file or document reflecting the change rather than "altering" the original document? Such a requirement greatly expands the universe of separate documents that a company must maintain over time.

Another example is the requirement, in §3.100(a)(4), that companies must maintain with an electronic signature "the name of the signatory, the date and time of signature, and any information that explains the meaning of the affixed signature." EPA has not been clear on what information is needed to explain the "meaning" of a signature.

³¹ 66 Fed. Reg. 46166.

³² See proposed §3.100(a)(6).

³³ A related provision is proposed §3.100(a)(7), which indicates that record changes must not "obscure previously recorded information." As a threshold matter, it is unclear how record "changes" differ from "alterations" of documents. Yet both provisions seem to suggest that original files, once created, may never be modified, requiring companies to generate and maintain a new document for each modification that is made.

Depending on how this provision is implemented over time, companies could be facing a variety of new obligations to link personnel and corporate governance information to EPA records.

Without further explanation, the full import of these anti-fraud measures cannot be understood from the face of the proposed rule. Based on the audit trail requirement alone, it is clear that CROMERRR will be an extremely expensive rule. The other provisions cited above only indicate that CROMERRR might be even more expensive than currently anticipated.

As part of its rationale for this rule, EPA has indicated that it intends to make electronic records equivalent to paper records from an accountability perspective. CROMERRR, however, is imposing requirements on electronic records that exceed what is now expected of paper records. This is a critical flaw in CROMERRR because the GPEA mandate seeks to put electronic records on a "level playing field" with paper records.

In several meetings EPA staff have indicated that paper records have various indicia of authenticity that do not apply to electronic records. As an example, they have offered the example of an enforcement case in which the examination of a paper record revealed that a party had obscured previous information with a "white out" erasure material.³⁴ EPA staff then posed the question of what would be the "equivalent of white out" in the electronic medium.

There are several levels of response to this concern. The "white out" example is a fairly primitive form of fraud. Parties who are seriously intent on committing fraud have any number of means of generating duplicate documents that will have all of the attributes of the original document. Many of these techniques are as old as the printed word. Detection of paper fraud often requires the assembly of evidence outside of what can be determined by examination of the alleged fraudulent document. This simple principle has been, and always will be, part of detecting fraud.

It is clear that the government does not currently impose requirements on the generation of paper documents that are analogous to what is contemplated in CROMERRR. In the modern world, paper documents are created by word processors. Yet EPA does not set standards for word processors, or certainly typewriters, that compare to what CROMERRR would require. There is no audit trail requirement or vague standard prohibiting "alteration" of paper documents as they are generated or modified.

Similarly EPA does not establish requirements for hand-written signatures that compare to what is being expected of electronic signatures. There always is some remote risk that a hand-written signature can be falsified and that such fraud would not be detected by EPA employees who are unfamiliar with the signatures of thousands of private parties. Yet companies do not have to keep and submit to EPA hand-writing samples for all of their employees who might ever sign an EPA document. The

³⁴ This example was posed by Agency staff in the public meeting held on January 17, 2002.

government simply has not considered that type of intrusive requirement as a costeffective way to prevent fraud.

The general point that must be drawn from these examples is that CROMERRR is not truly an effort to set standards for electronic documents that are equivalent to what is expected of paper documents. CROMERRR would hold electronic records to a higher anti-fraud standard than has ever been expected of paper documents.³⁵

Perhaps the core problem with EPA's approach to its anti-fraud concern in CROMERRR is that it has not provided any adequate analysis of the problem it seeks to remedy. The absence of a clear record on the nature of the "fraud problem" that EPA perceives makes it impossible to define the benefits of this rule in any meaningful way.³⁶

In the preamble to the rule and in general discussions in public meetings, EPA has expressed concerns about fraud that do not seem to bear a strong link to the solution proposed in CROMERRR. For example, EPA indicates that a purpose of CROMERRR is to assure that electronic records will be "admissible as evidence in a court of law to the same extent as a corresponding paper record." To our knowledge electronic records, particularly those maintained in the normal course of business in a company, are admissible in court assuming that reasonable steps are taken to authenticate the electronic record. If EPA has evidence that electronic records are not being accepted systematically, the situation should be documented and placed in the record. Then, EPA would need to explain how some aspect of CROMERRR would make those electronic records admissible.

EPA has discussed in public meetings its concerns about laboratory fraud arising in the preparation of studies used in EPA regulatory proceedings. Certainly EPA and DOJ have been involved in important cases to prosecute examples of fraud in this area. Yet it is not at all clear that the sweeping provisions of CROMERRR would have prevented such cases. Laboratory personnel can enter false data into databases by means of a pen or a keyboard. No software audit trail would detect false entry of data.

The issue of laboratory fraud is indicative of the need for a larger strategy if EPA decides to address fraud concerns. Laboratories generating data used in EPA programs are now governed by a strong set of "good laboratory practices" (GLP) requirements, and

³⁵ The DOJ Guidance is instructive on the government's general approach to addressing the comparability of paper and electronic records. The Guidance includes a discussion of the limitations of paper records and concludes with the following statement, "By contrast, effective electronic processes can overcome some of paper's weaknesses: electronic records, when properly organized or archived, are easier to store, search and retrieve than paper and allow for much broader access than paper documents." DOJ Guidance, at 6. These and other comments in the Guidance suggest that DOJ is interested in upgrading anti-fraud measures in the electronic medium over what is now required for paper records.

³⁶ While courts will provide agencies with some level of deference in establishing the rationale for a rule, the courts will demand that agencies provide evidence documenting the problem that a rule is intended to address. See <u>Bowen v. American Hospital Association</u>, 476 U.S. 610, 106 S.Ct. 2101 (1986).

³⁷ 66 Fed. Reg. 46169.

EPA laboratory inspectors make sure that these practices are met.³⁸ These standards include specific provisions addressing how studies should be documented and how records should be retained and reported. Perhaps more importantly, these standards also define a whole management system, including definition of lab personnel roles and responsibilities, a requirement for quality assurance units and establishment of standard operating procedures, that is designed to assure the integrity and quality of the laboratory's work.

If EPA is concerned about possible fraud in records that are submitted to the Agency or kept in private companies for EPA purposes, it is important that it take a broader look at the issue before focusing on software solutions through CROMERRR. Current practices in companies, which include the widespread use of electronic records, create many anti-fraud protections. These factors must be weighed in any serious EPA effort to understand the potential for fraud.³⁹

One of the more important trends to consider is the increasing integration between environmental monitoring devices and electronic data systems. As companies have moved toward newer monitoring technology, they are typically acquiring devices that automatically record environmental data electronically. This form of device has become particularly common where companies engage in some form of continuous monitoring. The sheer volume and complexity of data being generated by such devices must be recorded and maintained electronically.

From the fraud prevention perspective, this trend reduces the practical opportunities for fraud. These devices directly link environmental sensors to an electronic system that records the data. As a practical matter, it would be extremely difficult to manipulate the electronic data component of such a device without essentially corrupting the entire monitoring device. This is a clear example where the encouragement of electronic recordkeeping will actually enhance the integrity of the environmental data collection process.

As EPA recognized in its preamble discussion of ESIGN, many of the records that companies keep at their facilities to satisfy EPA regulations are also business records that have independent value for the company. In these situations companies have compelling business reasons to make sure that the information in their records is accurate.

For example, production records for certain chemical substances are relevant records to determine whether a company has complied with reporting obligations under the Toxic Substances Control Act or the Emergency Planning and Community Right to Know Act. Within the company, however, these production records are primarily viewed as core business records. Business managers have strong incentives to make sure those

³⁸ Primary examples of these standards would be 40 CFR Part 160 for the pesticide program and 40 CFR Part 792 for the toxic substances program.

³⁹ As a procedural matter, EPA should be considering these factors as a part of assessing the real risks of fraud for particular types of EPA-required documents, as indicated in the OMB Guidance and DOJ Guidance.

records are kept accurately and would not be expected to tamper with those records just to avoid an ancillary EPA requirement.

EPA should also not underestimate the strong inclination of companies and responsible officials in companies to comply with the law. Tampering with government-required records subjects responsible parties to legal sanctions. In some circumstances, criminal liability can arise. Very few individuals in companies are prepared to risk such sanctions in order to avoid EPA reporting and recordkeeping requirements.

The shift toward electronic records has actually made it more difficult for individual acts of fraud to go undetected. One of the results of electronic systems and strong information networks within companies is that a much larger universe of company employees have access to internal company files. As a general matter, fraud is easiest to commit when information is held by a small number of individuals. As electronic systems broaden employee access to information, it is more difficult for an individual to assume that an act of fraud would go undetected. Maintenance of a conspiracy to falsify data is simply more difficult in the transparent world of the Information Age.

The trends outlined here are just some of the many factors that EPA should be examining before it determines that the CROMERRR anti-fraud requirements are needed. Such an analysis would provide EPA with the necessary record to determine whether action is needed and also expand the range of options that might be considered to address a defined problem. It is not at all clear that a software solution such as CROMERRR is the most effective means to prevent fraud.

As indicated earlier, the absence of any analysis documenting the nature of EPA's perceived fraud problem is one of the core deficiencies in this rulemaking. The failure to provide such documentation is fundamentally inconsistent with the analytic process discussed in the OMB Guidance and DOJ Guidance on GPEA. Both of these documents indicate that electronic records can raise concerns about fraud, but neither attempts to provide any concrete documentation of the problem. Thus these documents are insufficient on their own as a basis for CROMERRR, particularly given the overwhelming costs associated with the rule. In the absence of better documentation of the fraud problem in the EPA context, CROMERRR cannot be justified.

Under these circumstances, the anti-fraud requirements in CROMERRR cannot satisfy the legal standard of the APA. EPA has not established a clear statutory authority for the provisions. The Agency has not documented a specific problem that needs to be addressed. As a result, EPA has not established that CROMERRR will be an effective remedy and certainly has not demonstrated that the rule is cost-effective in light of other approaches to preventing fraud. There has been no analysis of the issues that is consistent with the OMB Guidance or the DOJ Guidance.

As indicated earlier in these comments, EPA does not need to take any further regulatory action to comply with GPEA. If EPA decides that it wants to pursue the issue of fraud in electronic records independent of GPEA, several steps would be necessary. First, EPA should analyze carefully the evidence for this concern. The analysis should be grounded in EPA's own experience with fraud concerns. For example, the experience of EPA and state inspectors that implement EPA programs and thereby have reviewed the records of thousands of companies should be documented and shared publicly.

Second, EPA should also work more closely with the business community to understand the full range of records kept for EPA purposes. The nature of company software systems should also be assessed so that the Agency can appreciate the potential impact of a software-based solution to fraud concerns.

Third, if the views of DOJ play an important role in EPA's analysis, the Department should be asked to step forward and document its own concerns on this topic. Documents such as the DOJ Guidance are designed to pose issues and suggest a framework for resolving them. The DOJ Guidance is not, by itself, a sufficient record to support any regulatory action on this topic.

Fourth, if EPA determines that its fraud concern is warranted, a full range of options should be developed. These options should include measures beyond the software approaches found in CROMERRR. A critical aspect in the process would be a full assessment of the benefits and costs of the various options. Fifth, these options should then be opened to public review and comment, possibly through workshops or other public participation mechanisms. Based on this input, EPA can determine whether a formal rule on this topic makes sense.

CEEI does not believe that EPA should take any further action on the anti-fraud elements of CROMERRR until these steps have been taken. Since this issue is not an essential component of GPEA compliance for EPA, the Agency should take all necessary steps on this matter.

EPA Cannot Sustain the Rule's Provisions on Long-term Maintenance of Electronic Records

CROMERRR establishes a set of very demanding archiving standards. The proposed regulation calls for the archiving of electronic documents in a form that "preserves the context, meta data and audit trail." More specifically, companies must assure that, during the transfer of electronic records to a new computer system, all records and related meta data will transfer and "functionality necessary for use of records can be reproduced in [the] new system."⁴⁰

The ability to meet these standards in short time frames of 3-5 years might be possible. The difficulty with the requirement is that the commitment runs for the life of the record retention period specified in EPA regulations. Depending on the regulation, these record retention periods can run for very long periods of time, sometimes extending over decades.

Given the fact that computer systems are in a perpetual state of change, this archiving requirement becomes very problematic for companies. It is impossible to know today what the primary platform, operating system software or major software applications will be a decade from today. In today's world, experts advise that

⁴⁰ See proposed §3.100(a)(9).

companies risk data losses when they migrate computer files from legacy systems to new systems.⁴¹

Thus the CROMERRR archiving requirement raises fundamental issues about the technical feasibility of such a requirement. As other commenters will develop in more detail, experts in the field are doubtful that companies can meet the requirement for some of the long record retention periods found in EPA regulations. This challenge is not unique to the private sector. Governments will also face substantial questions about the ability to maintain their electronic records over time.

In light of these technological uncertainties, companies face difficult choices in how to meet the proposed archiving requirement. There are three primary choices. First, companies can set up "computer museums" in which they operate old hardware and software file systems, staffed by people who remain knowledgeable about legacy systems and supplied with adequate spare parts, to maintain EPA records that must be kept for long periods of time.

Second, companies can plan to convert their EPA electronic records to paper at the time that they decide to transfer their general files to a new computer system. ⁴² Third, companies can decide to disinvest in electronic records now in anticipation of the need to convert to paper at a later point in time. Whether a company would adopt either the second or third approach would depend on the nature of its record system, the EPA requirements it faces, its perceptions of future information technology and its approach to financial risk management.

In terms of the objectives of GPEA, none of these options make sense. Many companies will have serious doubts that they can count on the "computer museum" approach as a reliable alternative. It requires a substantial financial investment, the ability to hire and retain people willing to maintain old computer systems and access to replacement equipment for out of date computers. It is a high-risk option.

The other two options rely on converting electronic records to paper records. Such a result will impose substantial costs on the companies because the volume of EPA-required data currently held in electronic systems is quite extensive. The storage costs alone for the new paper records would be substantial. This result is precisely the opposite of what GPEA was intended to achieve. A requirement that pressures companies to move away from electronic records cannot be reasonably reconciled with GPEA.

Similarly this requirement cannot be reconciled with the PRA. As with other parts of CROMERRR, the archiving requirement does not reflect an effort to "reduce information collection burdens on the public." EPA will also not be able to meet its

All Rothenberg, Jeff, "Avoiding Technological Quicksand: Finding a Viable Technical Foundation for Digital Preservation," a Report to the Council on Library and Information Resources (January 1999), at 13.

⁴² This option assumes that EPA clarifies CROMERRR to allow such a practice. Right now the proposed rule is unclear on this point, particularly given the broad interpretation of "electronic record" in the rule.

⁴³ 44 U.S.C. §3506(b)(1)(A).

PRA certification requirements in at least two regards: (1) that the collection "reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency;" and (2) that the collection "is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who respond."

In light of this clear incompatibility between the archiving requirement and the statutes under which CROMERRR is written, EPA has an obligation to consider a broader range of alternatives. ⁴⁶ In particular, EPA should be reconsidering the underlying record retention periods in EPA regulations. The length of these retention periods is the primary driver determining the technical viability of the CROMERRR archiving requirement. The Agency's record retention periods have been developed incrementally, program by program, over the last 30 years. EPA has never reviewed these retention periods systematically on an Agency-wide basis.

A review of the current record retention periods in EPA regulations should address a variety of issues. From an environmental management perspective, how valuable is information about events that occurred several decades ago? For those retention periods that primarily serve compliance and enforcement purposes, how does the retention period relate to the statute of limitations for the particular requirement? If EPA is to encourage electronic commerce, how should it approach the interplay between reporting and recordkeeping for certain information? For example, should companies that have problems satisfying an electronic record archiving requirement be able to send their records to EPA for government storage?

As indicated above, EPA's decision to set standards for archiving of electronic records necessarily involves the Agency in a complex set of issues to reconcile the inevitable technological evolution of computer systems, EPA's long record retention requirements and the Agency's obligations under statutes like GPEA and PRA. EPA may decide to explore these complex issues in greater depth, but GPEA does not necessitate a resolution before October of 2003.

In its current form, however, the archiving requirements of CROMERRR cannot be legally justified. EPA has not identified any specific statutory authority or mandate to address the archiving issue. Assuming EPA's authority for the archiving requirement is GPEA and PRA, CROMERRR cannot be reconciled with the objectives of those statutes. The rule itself appears to impose requirements that are technically infeasible for many companies. In light of that technical limitation, EPA has not engaged in an adequate exploration of alternatives to meet the objectives of the statutes underlying CROMERRR.

⁴⁴ 44 U.S.C. §3506(c)(3)(C).

⁴⁵ 44 U.S.C. §3506(c)(3)(E).

⁴⁶ The OMB Guidance explicitly requires agencies to look at a broad range of alternatives if electronic record options are being frustrated. Specifically the Guidance states, "If the cost-benefit analysis of a proposed solution indicates that the electronic solution is not cost effective, the agency should seek to identify opportunities to reengineer the underlying process being automated. Occasionally, practices and rules under the control of an agency are based on factors or circumstances that may no longer apply." OMB Guidance, at 12.

For all these reasons, the archiving requirements of CROMERRR are not legally justified.

If EPA decides to step back from CROMERRR and develop a more strategic approach to the archiving question, the following steps would be warranted. First, EPA should catalog and analyze the record retention requirements found in its regulations. Each recordkeeping requirement should be examined to determine its core purpose. Second, EPA should survey the business community to understand how these records are currently maintained in electronic systems.

Third, if EPA views DOJ as a critical stakeholder in this issue, the Department should be asked to document its concerns with current archiving practices in companies. This documentation should be grounded in real experience in the EPA context. Fourth, EPA should develop a range of options on how it might address the issue. These options should extend beyond the software solutions proposed in CROMERRR to include such concepts as shortened retention periods.

Fifth, EPA should engage the public on these broad options. Based on this stakeholder input, EPA can then determine what options provide the best opportunity to assure appropriate archiving without discouraging wide-spread use of electronic recordkeeping.

Conclusion

With these comments, CEEI intends to indicate its strong opposition to the proposed rule. We believe that this version of CROMERRR is fundamentally flawed, as a matter of law and policy, and should be withdrawn.

At the same time, we do not want to suggest that CEEI is opposed to the general concept of electronic reporting and recordkeeping. As indicated at the outset of these comments, we believe that action to encourage e-government is in the long-range interests of all parties. For e-government goals to succeed, however, it is essential that government and the business community understand each other and develop solutions that are effective and practical. CEEI stands ready to work with EPA on constructive efforts to facilitate electronic reporting and recordkeeping.

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